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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/611,551	06/30/2003	Susan I. Shelso	10527-794001 / 02-260	5002
26161	7590	10/24/2006	EXAMINER	
FISH & RICHARDSON PC			TYSON, MELANIE RUANO	
P.O. BOX 1022			ART UNIT	
MINNEAPOLIS, MN 55440-1022			PAPER NUMBER	

3731

DATE MAILED: 10/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/611,551	Applicant(s) SHELSON, SUSAN I.	
	Examiner Melanie Tyson	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 16-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 16-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/12/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-3, 6-14, and 21-27 are rejected under 35 U.S.C. 102(e) as being anticipated by Cox et al. (US 2003/0212451 A1). Cox et al. disclose a grip constructed from polymeric material (polyether block amides; paragraph 79) for engaging a stent (Figure 18) comprising a tapered body region (40 and 100) having a first end (defined at a point midway between tapered edge 101) and a second end (defined at a point next to marker 42), a hub region (defined as the second half of tapered edge 101 extending through distal end 108, in which the region at the crest of tapered edge 101 has a diameter greater than the diameter of the first body region), and a radiopaque portion (104; paragraph 79). Cox et al. further disclose a catheter (refer to Figure 1) having an inner shaft (Figure 18, element 35) and a retractable sheath (52), a grip engaged to the inner shaft (35), and an expandable stent (80) comprising a plurality of struts disposed about the inner shaft (35) and engaged to, or mounted on, a portion of the body region of the grip. Figure 18 illustrates the sheath (52) has been retracted and the stent is in an expanded configuration positioned adjacent to the hub region. However, Figure 1

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illustrates the sheath overlying the stent, which clearly shows that the outer diameter of the first end of the grip is greater than the outer diameter of the stent when the stent is in an unexpanded configuration. Furthermore, the grip member disclosed by Cox et al. is inherently capable of reducing the longitudinal force the catheter exerts on the struts since the grip reduces the potential space between the inner catheter shaft (35) and the retractable sheath (52).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 4, 5, 19, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cox et al. Cox et al. disclose the claimed invention except for the specific hardness of the grip. It is well known in the art that materials such as polyether block amide may have a hardness within the ranges claimed. It would have been obvious to one of ordinary skill in the art at the time the invention was made to construct

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the grip with a hardness of about 60 to about 90, or of 70 to about 90, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

6. Claims 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cox et al. in view of Gunderson (US 2004/0204749 A1). Cox et al. disclose a grip as described above, however, do not disclose two grip members disposed about the inner shaft of the catheter. Gunderson teaches a stent delivery system comprising grips (Figure 8) for engaging a stent. Figure 8 shows a first grip (10) and a second grip (not labeled), with the second end of the body region of the first grip being substantially adjacent to the second end of the body region of the second grip. Figure 8 also shows a stent (26), where in the unexpanded state the first end portion of the stent (26) is engaged to at least a portion of the body region of the first grip (10), and the second end portion of the stent is engaged to at least a portion of the body region of the second grip (not labeled). Furthermore, Figure 8 shows the body portion of the stent overlies the second end of the body regions of both grips. It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize two grips as taught by Gunderson in the stent delivery system of Cox et al. in order to provide a stent delivery system that may reduce or eliminate occurrences of stent jumping, in turn improving the accuracy of stent placement within a vessel or other body space (paragraph 10).

Response to Arguments

7. Applicant's arguments filed 12 September 2006 have been fully considered but they are not persuasive (see rejection above). In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Gunderson teaches that many delivery systems provide the catheter shaft with one or more grips in order to provide a stent delivery system that may reduce or eliminate occurrences of stent jumping, in turn improving the accuracy of stent placement within a vessel or other body space (see paragraphs 8 and 10). Therefore, there is suggestion to combine these references and it would have been obvious to one of ordinary skill in the art to utilize two grips in the stent delivery system of Cox et al as taught by Gunderson.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571) 272-9062. The examiner can normally be reached on Monday through Thursday 9:00 a.m. - 6:30 p.m., alternate Fridays 9:00 a.m. - 5:30 p.m. EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson *MT*
October 18, 2006


ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
10/20/06